

## **REMARKS**

### **I. Non-Responsive Amendment**

On page 2, paragraph 1 of the Office Action mailed July 22, 2003, the Examiner stated that the Amendment filed May 15, 2003 was non-responsive because the new claims were directed to a non-elected invention and were not readable on the elected invention because the methods appearing in claims 5 – 33 are separate and patentably distinct from the method appearing in claims 1 – 4. The Examiner specifically pointed to the difference between claims 1 – 4 reciting a method of creating new tooth tissue and claims 5 – 33 reciting a method of generating a dental implant. The Examiner also stated that claims 5 – 33 do not contain the same steps as claims 1 – 4 as well as containing additional steps.

In response, Applicants have amended claims 5 – 33 to clarify that they are directed to the same invention as canceled claims 1 – 4. Accordingly, amended claims 5 – 33 recite “a method of generating tooth tissue” instead of “a method of making a dental implant” to make clear that claims 5 – 33 are drawn to the same invention as claims 1 – 4. Applicants respectfully submit that claims 5 – 33 may be broader than claims 1 – 4, but that they are indeed drawn to the same invention as that of claims 1 – 4. Claim 5 is very similar to claim 1, for example, claim 1 recites “[a] method to make new tooth tissue comprised of,” and claim 5 similarly recites, “A method of generating tooth tissue comprising....” The language of both preambles, therefore, is directed to the production of tooth tissue. Claim 1 recites, “a porous matrix consisting of synthetic, biodegradable biocompatible polymer of an appropriate shape and spacing of 50  $\mu$ m to 300  $\mu$ m between polymer fibers,” and claim 5 similarly, but more broadly recites “a biodegradable polymer scaffold.” Both claims, therefore, require a “matrix” or “scaffold” that is biodegradable. Claim 1 recites, “the matrix, when mixed with a suspension of tooth bud cells of

sufficient amount” and claim 5 recites, “applying tooth germ cells onto a biodegradable scaffold.” Both claims require the application of tooth cells to the “matrix” or “scaffold.” Claim 1 recites, “will generate tooth tissue following implantation into a host animal” and claim 5 similarly recites, “allowing the tooth germ cells to develop into tooth tissue for implantation.” Both claims, therefore, require the development of tooth tissue. The comparison of claims 1 and 5 above makes it clear that claims 5 – 33 are drawn to the same invention and are not separate or patentably distinct inventions from claims 1 – 4. In other words, the invention of claims 5 – 33 is not an independent invention from claims 1 – 4.

## **II. Status of the Application**

Claims 5 – 33 are presently pending in the application. In the Office Action mailed November 15, 2002, claims 1 – 4 were rejected under 35 U. S. C. § 102(e) as being anticipated by Burg (U.S. Patent Application Ser. No. 09/879,360). Claims 1 – 4 were rejected under 35 U. S. C. § 102(b) as being anticipated by Walter et al. (U. S. Patent No. 5,863,297). Claims 1 – 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Burg in view of Hammarström et al. (U.S. Patent No. 5,098,891) or Hammarström et al. (U.S. Patent No. 5,418,221). Claims 1 – 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walter et al. (US Patent No. 5,863,297) in view of Hammarström et al. (‘891) or Hammarström et al. (‘221).

Claims 1 – 4 were canceled in Applicants’ response filed May 15, 2003 without prejudice to the filing of any appropriate continuation application. Applicants respectfully submit that the amendments presented herein are supported by the specification and are not new matter.

Claims 5 – 33 were first presented in Applicants’ response filed May 15, 2003. Claims 5 – 33 were entered, but not examined by the Examiner. Claims 5 – 33 are amended to clarify that they are directed to the same invention as claims 1 – 4. Support for claim amendments can be found at least at page 18, line 2 of the specification. Below, Applicants address the rejections the Examiner made to claims 1 – 4 in light of the amended claims 5 – 33.

Applicants respectfully request reconsideration of the application and allowance of claims 5 – 33.

### **III. Rejection of Claims 1 – 4 Under 35 U.S.C. § 112**

On page 2, paragraphs 3 – 5 of the Office Action mailed November 15, 2002, the Examiner rejected claim 1 for not providing antecedent basis for “polymer fibers.” Claim 4 was rejected for reciting only a future intended use. In addition, claims 2 and 3 were rejected for their dependence from claim 1. Claims 1 – 4 have been cancelled. Accordingly, Applicants respectfully request withdrawal of the rejections.

### **VI. Claims 5 – 33 Are Not Anticipated by Burg**

On page 3, paragraph 8 of the Office Action mailed November 15, 2002, the Examiner rejected claims 1 – 4 as being anticipated by Burg. The Examiner asserts that Burg describes a method of making new dental tissue that uses a porous matrix made from a biocompatible biodegradable polymer. The Examiner also asserts that Burg anticipates the claims because claim 1 does not require the presence of tooth bud cells. Applicant’s respectfully traverse the Examiner’s rejections based on the newly submitted claims. Claims 1 – 4 have been cancelled

and the new claims require the presence of tooth germ cells. Accordingly, Applicants respectfully request withdrawal of this anticipation rejection.

**V. Claims 5 – 33 Are Not Anticipated by Walter et al.**

On page 4, paragraph 9 of the Office Action mailed November 15, 2002, the Examiner rejected claims 1 – 4 as being anticipated by Walter et al. The Examiner asserts that Walter et al. discloses a moldable implant material used to grow new dental tissue. The Examiner asserts that the method involves a porous matrix of biodegradable polymer that would inherently have the same properties of those disclosed in the application. In addition, the Examiner also asserts that Walter et al. also anticipates the claims because claim 1 does not require the presence of tooth bud cells. Applicants respectfully traverse the Examiner's rejection based on the newly presented claims. Claims 1 – 4 have been cancelled, and the new claims require the presence of tooth germ cells. Accordingly, Applicants respectfully request withdrawal of this anticipation rejection.

**VI. Claims 5 – 33 Are Not Obvious Over Burg in View of Hammarström et al. ('221) or Hammarström et al. ('891)**

At page 5, paragraph 11 of the Office Action mailed November 15, 2002, claims 1 – 4 stand rejected as being unpatentable over Burg in view of Hammarström et al. ('891) or Hammarström et al. ('221). The Examiner states that Burg teaches a method of using a porous polymer matrix as a scaffold to grow tissue. The Examiner states that Hammarström et al. ('891) and Hammarström et al. ('221) disclose methods for using the cells defined in claim 2 to grow new tooth tissue. The Examiner asserts that it would have been obvious to one of skill in the art to use the cells of Hammarström et al. ('891) or Hammarström et al. ('221) in the invention of

Burg. The Examiner further states that an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding in Burg with the “cells” of Hammarström et al. (‘891) or Hammarström et al. (‘221). Applicants respectfully traverse the Examiner’s rejection as to the newly presented claims.

Applicants’ claims are directed to a method of generating a dental implant using tooth germ cells. The claimed method includes applying tooth germ cells onto a biodegradable polymer scaffold.

Burg does not teach or suggest the use of tooth germ cells, whole cells, or even living cells. Instead, Burg teaches the use of a biodegradable support construct and a gel matrix made of a biocompatible material. The Examiner has chosen to modify Burg with the teachings of Hammarström et al. (‘891) or Hammarström et al. (‘221). Neither Hammarström et al. (‘891) nor Hammarström et al. (‘221), however, teaches or suggests the use of tooth germ cells, whole cells or living cells and accordingly, each fails to cure the deficiencies of Burg. Hammarström et al. (‘891) and Hammarström et al. (‘221) teach the use of a composition of a **cell extract** made from the enamel matrix, dentin, odontoblasts, and dental papille and not tooth germ cells, not whole or living cells. For example, see col. 5, lines 59 – 68 of Hammarström et al. (‘891) in which, “0.3 g of matrix (protein contents 27+4%) were slurried in 3 ml of 0.9%NaCl and homogenized under cooling with ice.... The homogenate was then freeze dried.” For another example, see col. 5, lines 26 – 41 of Hammarström et al. (‘221) in which the “tooth germs freed of the enamel organ are scraped to isolate and recover the desired enamel matrix, a semi-solid white mass being obtained which is homogenized with water to form a whipped cream-like consistency.” From the specifications of Hammarström et al. (‘891) and Hammarström et al. (‘221) it is clear that they teach the use of a cell extract or homogenate and not tooth germ cells.

The Examiner's combination of Burg with Hammarström et al. ('891) or Hammarström et al. ('221) therefore fails to teach or suggest all of the limitations of Applicants' claimed subject matter.

Additionally, Applicants respectfully submit that there is no motivation to combine Burg with Hammarström et al. ('891) and Hammarström et al. ('221). The Examiner's stated motivation for modifying the method of generating a dental implant of Burg with Hammarström et al. ('891) and Hammarström et al. ('221) is that an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding of Burg with the cells of Hammarström et al. ('891) and Hammarström et al. ('221). As Applicants stated previously, neither Hammarström et al. ('891) nor Hammarström et al. ('221) teach the use of tooth germ cells. Therefore, one of ordinary skill in the art would not be motivated to combine Burg with Hammarström et al. ('891) or Hammarström et al. ('221) in the way the Examiner suggested to arrive at Applicants claimed method including the use of tooth germ cells. Accordingly, Applicants traverse this basis for rejection.

In view of the above, Applicants respectfully request withdrawal of the obviousness rejection of the claims under 35 U.S.C. § 103(a).

**VII. Claims 1 – 4 Are Not Obvious Over Walter et al. In View of Hammarström et al. ('891) or Hammarström et al. ('221)**

At page 6, paragraph 12 of the Office Action mailed November 15, 2002, claims 1 – 4 stand rejected as being unpatentable over Walter et al. in view of Hammarström et al. ('891) or Hammarström et al. ('221). The Examiner states that Walter et al. teach the use of a porous polymer matrix as a scaffold to grow tissue. The Examiner states that Hammarström et al. ('891) and Hammarström et al. ('221) disclose methods for using cells defined in claim 2 to grow new

tooth tissue. The Examiner states that it would have been obvious to one of skill in the art to use the cells of Hammarström et al. ('891) or Hammarström et al. ('221) with the invention of Walter et al. The Examiner further states an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding in Walter et al. with the "cells" of Hammarström et al. ('891) or Hammarström et al. ('221). Applicants respectfully traverse the Examiner's rejection as to the newly presented claims.

Applicants' claims are directed to a method of generating a dental implant by applying tooth germ cells onto a biodegradable polymer scaffold.

Walter et al. do not teach or suggest the use of tooth germ cells, whole cells or even living cells. Instead, Walter et al. teach the use of a biodegradable support construct and a gel matrix made of a biocompatible material. The Examiner has chosen to modify Walter et al. with the teachings of Hammarström et al. ('891) or Hammarström et al. ('221). Neither Hammarström et al. ('891) nor Hammarström et al. ('221), however, teaches or suggests the use of tooth germ cells, whole cells or even living cells and accordingly, each fails to cure the deficiencies of Walter et al. Hammarström et al. ('891) and Hammarström et al. ('221) both teach the use of a composition of a **cell extract** made from the enamel matrix, dentin, odontoblasts, and dental papille, and not whole or living cells. For example, see col. 5, lines 59 – 68 of Hammarström et al. ('891) in which, "0.3 g of matrix (protein contents 27+4%) were slurried in 3 ml of 0.9%NaCl and homogenized under cooling with ice. . . . The homogenate was then freeze dried." For another example, see col. 5, lines 26 – 41 of Hammarström et al. ('221) in which the "tooth germs freed of the enamel organ are scraped to isolate and recover the desired enamel matrix, a semi-solid white mass being obtained which is homogenized with water to form a whipped cream-like consistency." From the specifications of Hammarström et al.

(‘891) and Hammarström et al. (‘221) it is clear that they teach the use of a cell extract or homogenate and not tooth germ cells. The Examiner’s combination of Walter et al. with Hammarström et al. (‘891) or Hammarström et al. (‘221), therefore, fails to teach or suggest all of the limitations of Applicants’ claimed subject matter.

Additionally, Applicants respectfully submit that there is no motivation to combine Walter et al. with Hammarström et al. (‘891) and Hammarström et al. (‘221). The Examiner’s stated motivation for modifying the method of generating a dental implant of Walter et al. with Hammarström et al. (‘891) and Hammarström et al. (‘221) is that an ordinary practitioner would have been motivated to create new tooth tissue using the type of scaffolding of Walter et al. with the cells of Hammarström et al. (‘891) and Hammarström et al. (‘221). As Applicants stated previously, neither Hammarström et al. (‘891) nor Hammarström et al. (‘221) teach the use of tooth germ cells. Therefore, one of ordinary skill in the art would not be motivated to combine Walter et al. with Hammarström et al. (‘891) or Hammarström et al. (‘221) in the way the Examiner suggested to arrive at Applicants claimed method including the use of tooth germ cells. Accordingly, Applicants traverse this basis for rejection.

Applicants respectfully request withdrawal of the obviousness rejection of the claims under 35 U.S.C. § 103(a).



### VIII. Conclusion


Applicants respectfully request reconsideration of the pending claims in view of the foregoing remarks. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

The Commissioner is authorized to apply any charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: \_\_\_\_\_

August 5, 2003

  
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